APPENDIX A

In the
United States Court of Appeals
for the Seventh Circuit

No. 98-1154

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

BALDEV RAJ BHUTANI, NEELAM BHUTANI, and ALRA LABORATORIES, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 93 CR 585–**John F. Grady, *Judge.***

ARGUED NOVEMBER 13, 1998
DECIDED APRIL 28, 1999

Before BAUER, RIPPLE, and EVANS, *Circuit Judges.*

BAUER, *Circuit Judge.* On February 12, 1996, after a ten week trial, a jury found the three defendants, Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc., guilty of a number of charges related to their manufacturing and distribution of mislabeled and/or adulterated generic pharmaceutical products. After various post-trial motions were

denied, the defendants filed a motion for a new trial based on newly discovered evidence and/or the government's violation of *Brady v. Maryland*, 373 U.S. 83 (1963). The district court granted the defendants' motion for a new trial on all counts of conviction based on the government's violation of *Brady*. The government now appeals that ruling. For the reasons set forth below, we reverse.

I. BACKGROUND

Baldev and Neelam Bhutani are the husband and wife team that owns ALRA Laboratories, Inc., a pharmaceutical company that produces generic prescription drugs. The trial primarily focused on the manufacturing and distribution process of two drugs produced by ALRA--Lactulose and K+10. Lactulose is a drug used to combat advanced liver disease, and K+10 is a potassium supplement.

On January 26, 1994, a federal grand jury filed a superseding indictment charging all three defendants with violations of 21 U.S.C. §§ 331(a), 331(e), 331(k), and 333(a)(2) and Baldev Raj Bhutani and ALRA with violations of 18 U.S.C. §§ 2, 371, 1001, and 1341. The indictment charged all three defendants with (1) adulterating and mislabeling their Lactulose products; (2) keeping improper records with respect to the Lactulose; (3) failing to meet the good manufacturing practice standards; and (4) introducing the adulterated Lactulose into interstate commerce--all with the intent to defraud and mislead. Additionally, all three defendants were charged with adulterating and failing to keep proper records with respect to their K+10 drug. Lastly, Baldev Raj Bhutani and ALRA were charged with providing false statements to various divisions of the Food and Drug Administration ("FDA") and obtaining money through fraudulent schemes. While the trial delved into all of the charges against the defendants, this appeal relates only

to a claim of the discovery of new, and the suppression of, evidence regarding the stability of Lactulose and the effect, if any, this had on the rest of the trial.

Lactulose is a drug that comes in a syrup form, much like the consistency of honey, that is used to treat the liver disease portal systemic encephalopathy. When an individual has this condition, the liver is unable to remove excess ammonia before it enters the bloodstream. Lactulose's function is to remove the ammonia from the colon and large intestine before it can enter the bloodstream. Lactulose is a disaccharide, meaning that it is a combination of two sugars. All drugs, including Lactulose, begin a degradation process after they are manufactured, which is why they are given expiration dates. As Lactulose ages, it breaks down into its component parts. Should it eventually decompose fully, a process that may take several years, then it would no longer be Lactulose, as the two sugars will have separated, rendering the drug ineffective. Only when the two sugars are combined may they act to remove ammonia from the colon and large intestine; neither sugar on its own can remove the ammonia. Without Lactulose, a person with portal systemic encephalopathy could slip into a coma caused by excess ammonia in the bloodstream.

One way of testing the stability of Lactulose is to measure its pH level. The pH scale measures the acidity or baseness of a chemical on a scale of 0 to 14. A chemical with a pH below 7 is an acid, while one with a pH above 7 is a base. At the time of the trial, the accepted pH range in which Lactulose was considered most effective, as set forth by the U.S. Pharmacopeia ("U.S.P."), also known as the "bible" of the pharmaceutical industry, was 3.0 to 7.0. The U.S.P. based this determination on stability data provided by various drug manufacturers to the FDA. As Lactulose ages and begins to degrade, it becomes more acidic, i.e. its pH drops. Thus, the

older Lactulose gets, the lower its pH reading will become. If the pH level becomes too low, the drug will no longer be effective to fight the liver disease.

The main focus of that portion of the trial concerning ALRA's production of Lactulose centered around two separate lots of the drug: lots 52-230 and 52-231. At trial, the government claimed, and the jury found, that employees at ALRA, at the direction of Baldev Raj Bhutani, adulterated these lots of Lactulose by "spiking" them with the foreign substance sodium hydroxide in order to conceal their age. Sodium hydroxide is a base, and, when combined with a more acidic substance, will raise its pH level. The government introduced evidence that ALRA employees opened individual bottles of Lactulose from lots 52-230 and 52-231, spiked them with sodium hydroxide, re-sealed the bottles and re-packaged them for distribution with an erroneous expiration date.

Lots 52-230 and 52-231 were manufactured in June of 1986. However, ALRA did not obtain approval from the FDA until July of 1988 to distribute the drug. When ALRA finally received approval to market its Lactulose, it aimed to distribute these two lots of Lactulose by September of 1988. The government presented evidence at trial that lot 52-231 had a pH level of 4.6 in February of 1988 and a pH level of 6.6 in August of 1988. This change represents a 100-fold increase in pH (a chemical with a pH of 4.6 is 100 times more acidic than a chemical with a pH of 6.6). In addition, the government showed that lot 52-230's pH level increased from 4.7 to 5.1 over the same period of time. It was agreed at trial by both government and defense expert witnesses that there is no naturally occurring process which will increase the pH level of Lactulose over time.

Based on the evidence presented at trial, which consisted of expert testimony, testimony from employees of ALRA,

and various data findings, on February 12, 1996, the jury found ALRA and Baldev Raj Bhutani guilty with respect to counts 3, 4, and 6 of the superseding indictment--charges relating to adulterating Lactulose, keeping inaccurate records, and sending the adulterated drug into interstate commerce. In total, the jury found ALRA guilty on 8 of 13 counts, Baldev Raj Bhutani on 7 of 13 counts, and Neelam Bhutani on 4 of 10 counts.

On July 5, 1996, after filing various motions for post-trial relief, the defendants filed a motion for a new trial based on newly discovered evidence and/or a *Brady* violation. They claimed that the government, at the time of the trial, had in its possession stability data from numerous drug manufacturing companies that showed that the effective range for Lactulose was not in fact 3.0 to 7.0, and that Lactulose was still perfectly effective with a pH level as low as 2.5. Furthermore, they asserted that the U.S.P. released a proposal in May of 1996 to change the effective pH range for Lactulose from 3.0 to 7.0 to 2.5 to 6.5. The defendants argued that, under the standards set forth in *Brady*, the government was obligated to turn this information over to them. They further asserted that this new data completely undermines the government's theory of the case that the defendants were willing to put their own personal profits ahead of the safety of the public by putting adulterated drugs on the market. Additionally, they claimed that the government's theory had a prejudicial "spillover" effect in the jury's findings of guilty on all of the counts, even those counts unrelated to the production of Lactulose. Thus, they contend that all of the defendants are deserving of a new trial on all of their convictions.

The district court agreed with the defendants. The court stated that the government's prevailing theme throughout the case was the defendants' blatant disregard for public safety by shipping adulterated drugs into the marketplace just so they

would not lose any profits by discarding the old, decomposed Lactulose lots. The court went on to say that since this new stability data showed that Lactulose was still effective at a lower pH level than the government represented at trial, the data tends to show that the defendants would have less of a reason to be nervous about a pH level of 4.6, and, therefore, had no need to spike the product to raise its pH level. Thus, the court determined that the government's suppression of this new stability data "seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4 and 6." *United States v. Bhutani*, WL 811689 at *14 (N.D. Ill. 1997). In addition, the court found that all of the counts of conviction were so entwined in the government's profit motive theory that it ordered a new trial for all defendants on all of their convictions, even those unrelated to the Lactulose charges. The government now appeals that ruling.

II. DISCUSSION

Appellate review of a district court's granting of a new trial in a criminal case is deferential. *United States v. Boyd*, 55 F.3d 239, 242 (7th Cir. 1995). However, when the review of a granting of a new trial based on a *Brady* violation revolves around a pure issue of law, our review is *de novo*. *United States v. Maloney*, 71 F.3d 645, 652-53 (7th Cir. 1995), *cert. denied*, __ U.S. __, 117 S. Ct. 295 (1996).

A. Brady Violation

Federal Rule 33 of Criminal Procedure allows a court to grant a defendant's motion for a new trial if it is required in the interest of justice. A motion for a new trial based on newly discovered evidence must be made within two years after final judgment. The district court granted the defendants' motion for a new trial because it found that the government did not fulfill its duties under *Brady* by not disclosing the stability data that was under the control of the FDA. We do not agree that the government committed a *Brady* violation.

Under Brady and its progeny, the government has an affirmative duty to disclose any evidence in its possession that is favorable to the defendant, and is material to either the issue of guilt or punishment. *United States v. Gonzalez*, 93 F.3d 311, 315 (7th Cir. 1996). Favorable evidence will be considered material if "its suppression undermines confidence in the outcome of the trial." *Id.* at 316 (quoting *United States v. Bagley*, 473 U.S. 667, 678 (1985)). The defendant does not have to show that it is more likely than not that the verdict would have been different if the evidence in question had been disclosed, but only that there is a "reasonable probability" that the outcome would have been different. *Gonzalez*, 93 F.3d at 316 (quoting *Kyles v. Whitley*, 514 U.S. 419,434 (1995)). Any nondisclosure of material exculpatory evidence by the government results in a violation of the defendant's due process rights.

Even though the government has an affirmative duty to disclose exculpatory evidence in its possession, it is not obligated to disclose "every possible shred of evidence that could conceivably benefit the defendant." *United States v. Hamilton*, 107 F.3d 499, 509 (7th Cir. 1997), *cert. denied*, __ U.S. __, 117 S. Ct. 2528 (1997). Nor does it have an

obligation to turn over evidence of which it has no knowledge. *Id.* Moreover, the government cannot be found to have suppressed evidence if the same information was available to the defendant through the use of reasonable diligence. *United States v. Morris*, 80 F.3d 1151, 1170 (7th Cir. 1996), *cert. denied*, 519 U.S. 868 (1996).

While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of *Brady* material will be imputed to the prosecution. *See United States v. Wood*, 57 F.3d 733, 737 (9th Cir. 1995); *United States v. Anderson*, 1998 WL 991216 at *3 (D. Kan. 1998). "The government cannot with its right hand say it has nothing while its left hand holds what is of value." *Wood*, 57 F.3d at 737.

The material that the defendants claim was suppressed by the government is data that was in the possession of the FDA at the time of trial which said that Lactulose was perfectly stable and effective with a pH level as low as 2.5. Based on this evidence, the defendants claim that as early as late 1995, the U.S.P. planned to recommend a proposed change in the effective range of Lactulose syrup from 3.0 to 7.0 to 2.5 to 6.5. Therefore, the defendants contend that this information which was in the possession of the FDA was helpful to their case because, had they known of the proposed change, they would have informed the jury of the same and argued that the Lactulose was still effective when the alleged spiking incident occurred. The defendants claim that this evidence undermines the government's theory of the case since the defendants would have had no reason to spike the lots in question. As it turns out, the U.S.P. eventually published its proposal to change the

effective pH range of Lactulose in May of 1996, three months after the jury's verdict.

While we agree with the defendants that information held by the FDA can, in this case, be imputed to the prosecution, we do not agree that the evidence in question is Brady material. Brady material must be (1) in the possession of the prosecution; (2) material; and (3) exculpatory. *United States v. Hartbarger*, 148 F.3d 777, 786 (7th Cir. 1998), *cert. denied*, __ U.S. __, 119 S. Ct. 1117 (1999). We disagree that the evidence in question was in the possession of the prosecution. The real evidence that the defendants rely on in their motion is the eventual publication of the U.S.P.'s proposal to lower the effective range of Lactulose. This was not published until well after the trial had ended. Simply because the FDA had stability data from other pharmaceutical companies does not mean that they had any knowledge that the U.S.P. was going to recommend the proposed change in Lactulose's effective pH range. The government cannot be held responsible for failing to disclose merely speculative evidence. United *States v. Agurs*, 427 U.S. 97, 109 (1976), n. 16. Since we find that the evidence in question was not within the possession of the government, we need not decide whether it was exculpatory or material. Therefore, we disagree with the district court that the defendants should have been granted a new trial based on the government's alleged *Brady* violation.

B. Newly Discovered Evidence

Even though the evidence in question was not within the possession of the prosecution, the defendants may, nevertheless, be entitled to a new trial based on newly discovered evidence, an alternative theory raised in their motion for a new trial. The standard for determining whether a defendant is entitled to a new trial based on newly discovered evidence is different from

that of determining whether one is entitled to a new trial because of a Brady violation. We have evolved a four part test to determine whether a defendant's motion for a new trial based on newly discovered evidence should be granted. The defendant must show that the evidence at issue (1) came to his knowledge only after the trial; (2) could not have been discovered sooner through the use of due diligence; (3) is material and not merely cumulative or impeaching; and (4) would probably lead to an acquittal in the event of a new trial. *Gonzalez*, 93 F.3d at 315.

The defendants argue that the U.S.P.'s recommendation to lower the effective range of Lactulose would have been helpful to their case because it would have destroyed the prosecution's profit-motive theory. They argue that since Lactulose does not lose any of its laxative effect and is still effective with a pH as low as 2.5, then there was no reason to spike the lots in question. The district court agreed with them. We find that both the defendants and the district court mischaracterized the prosecution's argument.

The district court's decision relies heavily on the idea that the government portrayed the defendants as profit-hungry monsters who were willing to put the public's safety at risk in order to make a buck by putting ineffective drugs on the market. The court said that the government argued that the defendants spiked their Lactulose lots because they wanted to mask the fact that the product would soon be unfit for use. *Bhutani*, 1997 WL 811689 at *12 (N.D. Ill. 1997). Thus, the district court concluded that the new evidence undermines the government's profit-motive theory and the jury could very well have reached a different conclusion had it known of the new effective range.

We agree that the government's theory was that the defendants were driven by the desire to make a profit, but, after reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit, or close to unfit. What the government did argue was that the defendants spiked the Lactulose lots because the lots were old and they wanted to conceal their age to make them look like newer lots of Lactulose produced by ALRA. The reason for this is that the FDA has determined that Lactulose should be marketed with an expiration date that is 18 months after its manufacture. Here, the lots in question were all manufactured in 1986 and not distributed until 1988. In order for the defendants to sell their product, it had to conform to FDA standards. Thus the defendants had to conceal the *age* of the product. They did this by raising the pH levels and marking the lots with expiration dates of September 1989. The government did not argue that the pH level in the lots in question ever dropped below 3.0. In fact, when the government's expert witness, Dr. Hicks, was questioned by defense counsel, he stated that the pH levels were never outside of the effective range. Thus, it was the defense, and not the government, that put the effective range at issue in the first place. Neither Dr. Hicks, nor any other government witness, ever testified that the Lactulose in question was ineffective. The adulterated lots had the potential of becoming unsafe while in the marketplace with an inaccurate expiration date, but were not necessarily unsafe at the time of distribution. The government argued that the defendants put the public's safety at risk by supplying adulterated products, not necessarily ineffective ones.

Throughout the trial, the defendants contended that the spiking incident never occurred. However, based on all of the

evidence, the jury simply believed the prosecution's case over the defendants'. The Prosecution presented expert witnesses who testified that there is no naturally occurring process which can reverse the trend of Lactulose's degradation. In addition, the government called former employees who participated in the spiking incident to describe the process that was used in adding the sodium hydroxide to the Lactulose syrup. Those employees described, in detail, the "assembly line" type procedure that was used in opening the Lactulose bottles, injecting them with sodium hydroxide with a turkey baster type instrument and later a syringe, re-sealing the bottles, and repackaging them with falsified expiration dates. The government also presented employee time cards with extensive overtime recorded on the days the spiking incident occurred. Lastly, these employees testified that Baldev Raj Bhutani oversaw and authorized the entire operation. The defense had ample opportunity to cross examine these witnesses, and indeed they did. The fact that the U.S.P. subsequently proposed a lower effective pH range for Lactulose is of no consequence to the case since the government never argued that the Lactulose's pH was outside of the effective range, or even close to being outside the range.

The trial judge properly instructed the jury on what it must unanimously find in order to convict the defendants on counts 3, 4, and 6. Count 4 charged that the defendants, with the intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the Lactulose lots in question. In order to find the defendants guilty, of this count, the jury had to unanimously find that the defendants injected the lots with sodium hydroxide. The jury unanimously found this with respect to Baldev Raj Bhutani and ALRA, but not Neelam Bhutani. For count 3, the jury had to find that the lots of Lactulose were adulterated. The judge instructed the jury that the drug could have been adulterated in one of three ways. First, it could have been

produced in a way that did not conform with the good manufacturing practices. Second, it could have decomposed to such a point that it no longer met applicable testing specifications. Third, the defendants could have added sodium hydroxide to it. The jury only had to find that any one of those three events occurred for the drug to be adulterated. The same is true for count 6.

Arguably, the new proposal by the U.S.P. could have shown that the Lactulose still met specifications even though it had degraded some. However, since the jury found in count 4 that the defendants added sodium hydroxide to the Lactulose, then it implicitly found that the drug had been adulterated with respect to counts 3 and 6 as well. Its finding in count 4 acts as an independent basis of a finding of adulteration for counts 3 and 6. Therefore, while the new data could show that the Lactulose had not degraded to the point of making it unsafe, the jury nonetheless found that the drug was adulterated by the addition of sodium hydroxide. Thus, the defendants are not entitled to a new trial for counts 3, 4, and 6 based on newly discovered evidence.

C. The Spillover Effect

Lastly, the district court ruled that all of the defendants were entitled to a new trial on all of their convictions, even those unrelated to Lactulose, because all of the charges were so entwined with the government's profit-motive theory that it influenced the jury's decision on the other counts. Since we have determined that the defendants are not entitled to a new trial for counts 3, 4, and 6 because of the new evidence, it necessarily follows that there could be no spillover effect on the other counts. Even if we were to find that the defendants were entitled to a new trial for the Lactulose charges, the other convictions were based on an entirely different set of facts and

conduct for a different drug altogether. These convictions were based on the manufacturing of K+10 and how a foreign substance was accidentally introduced into the mixing process, yet the drug entered the marketplace regardless. Even if the new evidence would have led to a different outcome in counts 3, 4, and 6, the new evidence has absolutely no relation to the conduct for which the defendants were found guilty in the manufacturing and record keeping of K+10. These violations contain completely different elements and are not related to the U.S.P.'s new proposal whatsoever. The jury found beyond a reasonable doubt that the defendants were guilty of these counts regardless of the Lactulose charges as evidenced by the fact that it did not find that Neelam Bhutani was guilty of counts 3, 4, and 6, but that she was guilty for her role with respect to the K+10 offenses. Therefore, the defendants are not entitled to a new trial on these additional counts.

III. CONCLUSION

For the reasons set forth above, we REVERSE the district court's ruling that the defendants are entitled to a new trial on all of their convictions based on a *Brady* violation or newly discovered evidence and REMAND to the district court with orders to reinstate the verdicts of conviction and to sentence the defendants to appropriate terms as prescribed by the Sentencing Guidelines.

A true Copy:

Teste:

Clerk of the United States Court Of Appeals for the Seventh Circuit

APPENDIX B

UNPUBLISHED

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, *Plaintiff,*	)
v.	) No. 93 CR 585
BALDEV RAJ BHUTANI, NEELAM BHUTANI, and ALRA LABORATORIES, INC., *Defendants.*	)

MEMORANDUM OPINION

Pending before the court is "the Motion of the Defendants for a New Trial Based on Newly Discovered Evidence and/or Violation of Brady v. Maryland." The motion will be allowed, for the reasons explained in this opinion.

Procedure

The defendants in this case are Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc., a corporation Baldev and Neelam Bhutani own and operate. ALRA is in the business of manufacturing and distributing generic drug products. The indictment included allegations that the defendants conspired to commit and did commit certain offenses involving adulteration and misbranding of various drug products. The counts of the indictment that are

primarily involved in the pending motion for a new trial are Counts 3, 4 and 6. The gist of these counts is that the defendants fraudulently adulterated quantities of Lactulose Syrup by adding an "undocumented substance," namely, Sodium Hydroxide. The jury found ALRA and Baldev Bhutani guilty on these three counts and was unable to reach a verdict as to Neelam Bhutani. [1]

Lactulose Syrup is used for the treatment of a serious liver disease known as portal systemic encephalopathy. This condition, caused by liver failure, results in ammonia reaching the bloodstream and the brain rather than being excreted. It can cause hepatic coma or death. Lactulose Syrup "reduces the absorption of the ammonia from the colon and thereby decreases the load that goes to the poor old liver that's injured and can't handle it. So that less ammonia is going to get to the blood that goes to the brain." In this way, the Lactulose "prevents [portal systemic encephalopathy] if it hasn't happened and it reduces it if it's already there."[2]

Lactulose is a "disaccharide," or a combination of two sugars, and it must reach the colon in that form if it is to absorb the ammonia and do its laxative work. It is important, therefore, that Lactulose ingested by a patient not be broken down, or degraded, into its separate components. If it is, it

---

[1] Neelam Bhutani, therefore, would have a new trial on these counts in any event, but she argues that because of the newly discovered evidence, there is a "spillover effect" which entitles her to a new trial, as well, in regard to the other counts on which she was found guilty. This argument is addressed at pp. 28-30, infra.

[2] Testimony of Dr. John Senior, pp. 26-27.

will be absorbed in the small intestine and never reach the colon.[3]

Lactulose which is in its optimal, disaccharide condition is said to be "stable." A way of testing the stability of the solution is to determine its "pH" level, that is, its point on the range between acid and base. The scale runs from 0 to 14, with 7 being considered neutral. The lower the pH, the more acidic the solution will be. At some level, a pH reading will be so low as to indicate a breakdown of the Lactulose into its constituent monosaccharides. According to the testimony of Dr. Hicks, Lactulose is "optimally stable at somewhere between a pH of 4 to 5."[4]

The government's contention at trial was that defendants' Lactulose lots in question were old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective or close to becoming medically ineffective. It was for this reason, according to the government, that defendants injected these aged Lactulose lots with Sodium Hydroxide, a base, in order to raise the pH of the Lactulose and make it appear safe for use. Adding pH to decomposed Lactulose would not, of course, restore it to its disaccharide form; it would merely mask the fact that the decomposition had occurred.

The motive was profit, said the government. The defendants did not wish to discard the decomposed Lactulose, so they disguised it in order to make it saleable. This theme of cutting corners and making profits in disregard of public

---

[3] Testimony of Kevin Hicks, p. 34.

[4] Id., p. 34.

health was emphasized to the jury as early as the prosecutor's opening statement:

> This is a case about a pharmaceutical company that put contaminated drug products on the market and lied to the Food and Drug Administration about it. It is about the decisions of the company's president and a company's quality control director to violate the rules governing the pharmaceutical industry. It is about their decisions to cut corners in the manufacturing and in the testing of human pharmaceuticals and to put adulterated and misbranded prescription drug products on the market.
>
> Why? To make money. Because cutting corners saved money and selling defective products raised their own profits. This case is about a corporation and its two officers' repeated decisions to put their personal profit ahead of the public health, and their decisions to line their own pockets instead of ensuring that patients, their customers, were receiving safe and effective prescription medication.
>
> * * *
>
> Again, why did they do this? To make money. This case is about a corporation and its officers' repeated decisions to put money over the quality of their product, to line their own pockets instead of ensuring that their customers were taking safe and effective medicine and to put their private profit over the public health.

* * *

Now through the next few weeks, the government will not attempt to review with you everything that happened to ALRA over a five-year period. We won't tell you what happened each and every day. But what we will do is we will bring witnesses before you, former employees of Alra, who will tell you about some of the things that went wrong at the firm. We will tell you what happened on those occasions when Baldev Raj Bhutani and Neelam Bhutani chose to break the rules and when they directed their employees-to ignore . the ANDA [ABBREVIATED NEW DRUG APPLICATION] procedures and violate the CGMP [CURRENT GOOD MANUFACTURING PRACTICES] regulations and when they allowed defective products to enter the market.

Over the next few weeks we will present to you six incidents, and the incidents document what went wrong at the firm, what violations occurred.

The first incident that you will hear about involves a drug product called Lactulose, and Lactulose is a prescription drug. It is a liquid and it comes in 8 and 16 ounce bottles and is used for patients who have a disease called portal systemic encephalopathy. And it is essentially people who have extensive liver disease or liver failure. And the product is used to draw contaminants out of the body and

to prevent coma. That is what it says on the label.

* * *

That is not all they did. Before they shipped the product out the door, they took another important step to cover up the fact that they were shipping expired product. Oftentimes large buyers or wholesalers of generic drug products will test a product once it has been received, and they will test a product like Lactulose for something like pH or acidity, and these tests are designed to assure that the product is not degrading, that it is still within specification.

Baldev Raj Bhutani and Neelam Bhutani knew this. In fact, ALRA was selling these products to large pharmaceutical wholesalers including the AARP and Biolob.

So what do the Bhutanis do? The defendants instructed their employees to open up the bottles of Lactulose, those 1986 bottles, and inject a chemical called sodium hydroxide into the bottles in order to raise the pH and make it appear that the product had not, in fact, degraded.

They added this undocumented component through an unapproved procedure to mask or to hide the underlying degradation of the product. So even when a diligent consumer like a wholesaler might test a product, they could not know that the product had degraded,

and the expiration date the defendants had put on the label was a lie. The defendants chose to label a product with an expiration date more than three years after its date of manufacture even though they knew the product was only approved for 18 months. They injected a chemical into the product to mask the fact that the product had degraded.

Why? Because destroying the product would cost money, and selling the expired product would make money. Now, that is what the government will show you with respect to this first incident, and you will see proof in documents and you will hear the evidence through the testimony of witnesses.

You will first hear from Dr. Kevin Hicks, and he is the carbohydrate chemist. He is an expert on Lactulose, and he will tell you that Lactulose is a type of carbohydrate called a disaccharide, and this disaccharide degrades over time. And as time passes, the product breaks down into its component parts. And you can detect this degradation of the product by testing its pH. And as the product degrades, the pH will decrease.

And Dr. Hicks will tell you that adding the chemical, sodium hydroxide, before shipping a product out would simply mask or hide the degradation. It would not reverse it. It would not make the product new again.

> In addition, another expert, Dr. John Senior, the gastroenterologist, will tell you that he treated hundreds of patients with this disease of portal systemic encephalopathy, the liver failure, and that he prescribes Lactulose to treat patients. He will tell you that if a product is sufficiently old and the disaccharide has degraded in to its component products, the Lactulose simply will not work. The drug will be ineffective in treating the patient's advanced liver disease. And a physician may have to resort to other measures to prevent coma.[5]

At trial, the government called a number of former ALRA employees who testified that at the direction of the Bhutanis, they injected sodium hydroxide into bottles of Lactulose Syrup, using syringes. The Bhutanis denied on the witness stand that any such thing occurred.

On the question of whether the Lactulose in question was likely to have been medically ineffective at the time it was shipped, the government elicited the following testimony from Dr. Senior:

> Q. Does the Lactulose have to be in the disaccharide form in order to work?
>
> A. Of course. If it's not in the disaccharide form it's not Lactulose.

---

[5] Smolover Opening Statement, pp. 4-5, 12-14, 16-17, 20-21.

Q. If Lactulose is degraded into monosaccharide components, would it work to treat portal systemic encephalopathy?

A. No, it won't work if it's degraded or split because the split products of Lactulose are fructose and galactose, which are easily-absorbed sugars. They're gone; they never get to the colon.

Q. So, if the Lactulose has been split before you give it, it will not reach the colon.

A. Well, of course. I mean, if the Lactulose is effective it is Lactulose. If it's not Lactulose, then it doesn't work.

Q. Conversely then, would Lactulose be less effective if it had broken down, or a substantial portion had been broken down?

A. Of course it would be less effective if it had been broken down. Of course.

Q. Would lactulose, if it had degraded into its component parts, be effective in treating portal systemic encephalopathy?

A. No, it would not.

Q. Why would that be?

A. Because the degraded products would not reach the colon; they would be absorbed by the small intestine before the material

reached the colon. So the bacteria in the colon would have nothing to work on. So they could not acidify, they could not cause a laxative effect.

Q. And would a physician be able to ascertain what was wrong if Lactulose had broken down into its disaccharide form?

A. That makes it very hard on the physician, because a lot is going on in these sick patients. They have got a failing liver, they often have -- they are now getting failure of the brain function, they often have kidney failure that goes with the liver failure. They've got a lot of problems. And the last thing a physician is going to think of when he prescribes a drug is it isn't what it's supposed to be. That's not something that would occur to a physician right away. He would not quite know what to do if it wasn't working.[6]

The prosecutor in her closing argument drove home to the jury this testimony of Dr. Senior as demonstrating the dangerousness of the Lactulose that had been injected with the Sodium Hydroxide:

Now, after you heard about all the chemistry, you heard from a physician, and that was Dr. John Senior. And he told you the medical consequences of this degradation and why in very human terms, this all matters.

---

[6] Testimony of Dr. John Senior, pp. 27-29.

Dr. Senior was that gastroenterologist who has practiced for 30 years. And he explained to you that Lactulose is used to treat a condition called portal systemic encephalopathy. It's basically a condition resulting from serious liver disease. And he told you about his experience treating 3,500 patients.

He explained to you that in patients with this condition in their livers, their liver stops to function because the liver cannot remove the ammonium from the blood; and, without intervention, the ammonium in the blood reaches the brain, compromises brain function and can cause coma and sometimes death.

Lactulose is used to substitute for a healthy liver. Lactulose works in the colon, the large intestine, to bind with the ammonium and excrete it before it can enter the bloodstream.

But as Dr. Senior pointed out, the Lactulose has to reach the large intestine in order for it to work. If the Lactulose is already broken down, if it is already degraded into its monosaccharide form, the monosaccharides will be absorbed in the small intestine, they'll be digested, and the Lactulose in its disaccharide form will never reach the colon, the site of the therapeutic treatment. And it will be rendered ineffective in treating patients with hepatic coma or portal systemic encephalopathy.

And Dr. Senior told you that a physician would not surmise that something was wrong with the Lactulose. They'd be forced to switch to another therapy, another treatment, that could potentially pose more risk.

And Dr. Senior pointed out that the less concentrated the Lactulose, the less disaccharide form of the Lactulose in that bottle, the less effective it's going to be in treating the disease condition for which it should be used: portal systemic encephalopathy.

Now, you've heard all this evidence about the reworking of the batches. You have heard all these -- witness after witness tell you about the sodium hydroxide injection. You've heard about the labeling of September '89, where that date came from and how it was put on the bottles.

And we've talked to you about the motive in committing these crimes. The lots were reworked because the defendants didn't want to lose money and throw these expired lots away. They injected the chemical to mask the degradation, so the consumer would not know that the product has degraded.

They failed to document the rework in the batch records, so that the FDA, when examining the records, wouldn't know what had happened.

> And they put a label on the product that was more than three years after the date of manufacture, even though they knew that the appropriate expiration date at any time was not more than 18 months.
>
> And they did so to raise money, because destroying that old product would cost them money and selling expired product would raise profits.[7]

The government's "Version of the Offense" which the prosecutors submitted to the probation officer for inclusion in the presentence report shows that the government believed it had proved the defendants had injected the sodium hydroxide to conceal the medial ineffectiveness of the Lactulose:

> The expert testimony of a carbohydrate chemist and gastroenterologist at trial indicated that these lots posed a risk to the public health, as degraded Lactulose will not be effective in treating portal systemic encephalopathy. Left untreated the condition can be life threatening.[8]

The government went on to state its position that the defendants should receive a 2 point enhancement under sentencing Guideline 2Fl.1(b)(4) because the offense "involved the conscious risk of serious bodily injury."

---

[7] Smolover closing, pp. 40-42.

[8] Government's Version of the Offense submitted as to the defendant ALRA, dated April 22, 1996, p. 9. (Identical statements were submitted for the two individual defendants).

The Government's gastroenterology expert testified that Lactulose is used to treat a condition called portal systemic encephalopathy, caused by advance liver failure. The Lactulose must reach the colon in its original disaccharide form in order to bond with ammonium and rid the system of this toxin. If the Lactulose has degraded it will break into monosaccharides and be absorbed in the small intestine. It will not reach the colon at all. The ammonium, in turn, will remain in the blood, reach the brain, and may cause hepatic coma or even death. The expert further testified that a physician treating a patient with this condition is unlikely to presume that the Lactulose is defective. The doctor is thus likely to employ more radical drug therapy in attempting to treat the portal systemic encephalopathy and resulting coma. Finally, the defendant's own chemistry expert testified that the injection of sodium hydroxide itself can pose significant risk to those consuming the product and the chemical may exist in a concentrated form in pockets of the liquid and may be lethal.[9]

The Pretrial Discovery

Extensive pretrial discovery motions were filed by the defendants. The court had the impression from the government's representations that it was furnishing everything

---

[9] Id. at 16-17.

the defendants were entitled to, and more. At one point the government filed a response stating that

> [f]or over fifteen months, the government has complied with, and far exceeded, its discovery obligations under Rule 16 of the Federal Rules of Criminal Procedure and Local Rule 2.04. The government promptly turned over all Brady material and provided the Defense with access to and copies of, all records in the possession of government counsel to which the Defense was even remotely entitled.[10]

The Response went on to state that

> (a]ll Brady (i.e., potentially exculpatory) material has been produced. In making its Brady production, the government has taken a very expansive approach and produced any materials that are simply "favorable" to the Defense, even if not 'exculpatory.' Of course, the government recognizes its continuing obligation under Brady and will produce any additional materials of which the government becomes aware.[11]

THE DEFENDANTS' MOTION

The evidence at trial was that the pH range recommended for Lactulose by the U.S. Pharmacopeia ('U.S.P.') was

---

[10] Government Collective Response filed August 23, 1995, at 2.

[11] Id. at 9.

between 3.O and 7.0. The recommendation by the U.S.P. is based on stability data made available to it by drug manufacturers. The same data is submitted by the manufacturers to the U.S. Food and Drug Administration, the agency which investigated this case and worked closely with the Department of Justice throughout its prosecution.

The verdict of the jury was returned on February 12, 1996. In June of 1996, the U.S.P. issued a bulletin that proposed revision of the pH range downward from 3.0-7.0 to 2.5-6.5. The explanation given by U.S.P. for the proposed change was that:

> Based on information received that stability data has shown a downward trend in pH over time, it is proposed to revise the pH range in this monograph. The proposed pH range is reported not to have any significant impact on the safety and quality of this product: it does not in any way effect the laxative properties of the product, and it does not affect the level of the related substances.

Based on this information, the defendants filed the present motion, contending that the stability information should have been disclosed to the defendants inasmuch it undercut the government's contention that the Lactulose involved in Counts 3, 4, and 6 was at or near the point of medical ineffectiveness at the time it was distributed by the defendants:

> Specifically, it was alleged and repeatedly argued that, because the pH of the lactulose syrup that had been manufactured in 1986 was dropping close to a level 3, such lactulose was in fact decomposed and thus, the therapeutic

> effects of the lactulose were being lost and the health of consumers was therefore jeopardized. It was the Government's position that, as the pH dropped below 3, certain portions of the lactulose or its parts were being dissipated to impact quality. Thus, it was theorized that if a patient was not responding well to lactulose treatment, a physician had no way of knowing whether it was from the patient's condition or whether the lactulose was no longer effective.
>
> Accordingly, the Government's thrust was not merely to demonstrate that sodium hydroxide, an approved additive, was added to the lactulose in 1988, but to prove that the addition of sodium hydroxide was to mask lactulose decomposition, thereby endangering the lives and safety of the consumer simply to profit the Defendants. However, recently discovered evidence not only provides significant support for the Defendants' position that the lactulose was safe, but also demonstrates that the Government knew it was safe and still argued the contrary to the jury and this Court.[12]

The motion has been pending for a considerable period of time, due in part to the fact that, over the government's objection, the court allowed the defendants' discovery in connection with the motion and required the government to produce the stability records filed with the FDA by the

---

[12] Memorandum in Support of Motion for New Trial Based on Newly Discovered Evidence and/or in Violation of Brady v. Maryland, pp. 1-2.

Lactulose producers for the years underlying the U.S.P. proposal. These stability records do indeed support the proposal and demonstrate that Lactulose with a pH as low as 2.5 is stable and medically effective. The government does not contend otherwise, nor does it even contend that the FDA was unaware of the contents and significance of these records prior to trial. However, it makes a variety of arguments as to why, as a matter of law, the defendants are not entitled to a new trial.

THE LEGAL ARGUMENTS

Defendants have moved for relief under Brady v. Maryland and Rule 33 of the Federal Rules of Criminal Procedure. The parties have not specifically addressed the question of which test applies in the event there are any differences between Rule 33 and Brady. The defendants rely mainly on cases decided under Brady, while the government's emphasis is largely on cases decided under Rule 33. There is a difference between the two approaches, and it will be useful to point out that difference before proceeding to a discussion of the parties' arguments.

Federal Rule of Criminal Procedure 33 permits a defendant to request a new trial based on "newly discovered evidence." See Fed. R. Crim. P. 33 (stating that "[a] motion for a new trial based on the ground of newly discovered evidence" may be made before or within two years after final judgment). In most cases, a defendant making such a request "must satisfy a stringent multi-stage test." United States v. Gootee, 34 F.3d 475, 479 (7th Cir. 1994). The defendant must show that the evidence in question (1) came to his knowledge only after trial; (2) could not have been discovered sooner through the exercise of duc diligence; (3) is material and not merely impeaching or cumulative; and (4) would

probably lead to an acquittal in the event of a new trial. United States v. Gonzalez, 93 F.3d 311, 315 (7th Cir. 1996); United States v. Severson, 49 F.3d 268, 271 (7th Cir. 1995); United States v. Young, 20 F.3d 758, 763 (7th Cir. 1994). This multi-part test is also known as the "Berry rule," since it was first articulated in a state court case of the same name over 100 years ago. 3 Charles Alan Wright, Federal Practice and Procedure § 557, at 315 (2d ed. 1982 & Supp. 1997) (citing the 1851 Georgia case of Berry v. State).

Significantly, however, the Berry rule applies only to "ordinary" motions for new trials based on claims of newly discovered evidence. Id., at 316. Different, less restrictive rules apply if a motion for a new trial is based on a claim of nondisclosure or suppression of evidence by the prosecution. Id.; See also id., § 557.2, at 352-53 ("[A] situation in which it is clear that the Berry rule does not apply is where the government has failed to disclose evidence favorable to the defense."). As a result, a Rule 33 motion containing a "suppressed evidence"claim is governed by the standards set forth in Brady v. Maryland, 373 U.S. 83 (1963), and its progeny. See United States v. Kelly, 790 F.2d 130, 133 (D.C. Cir. 1986) (specifically acknowledging that the Berry rule "does not . . . govern motions f or a new trial when the newly-discovered evidence indicates that the original trial was marred by a sixth amendment or Brady violation"). Most federal cases do not expressly discuss the difference between "ordinary" Rule 33 motions and Rule 33 motions based on Brady, but the cases at least implicitly recognize the distinction by applying Brady in lieu of the Berry rule. See, e.g., Gonzalez, 93 F.3d at 315-16; United States v. Veras, 51 F.3d 1365, 1374-75 (7th Cir.), cert. denied., 116 S. Ct. 540 (1995) ; Young, 20 F. 3d at 764; See also, e.g., United States v. Wong, 78 F.3d 73, 79 (2d Cir. 1996); United States v.

Thornton, 1 F.3d 149, 158 (3d Cir. 1993); United States v. Stephens, 964 F.2d 424, 435-36 (5th Cir. 1992).

The criteria for relief under Brady are as follows. A defendant must establish that (1) the prosecution suppressed evidence; (2) the evidence was favorable to the defense; and (3) the evidence was material to an issue at trial. United States v. Morris, 80 F.3d 1151, 1169 (7th Cir.), cert. denied, 117 S. Ct. 181 (1996); United States v. Payne, 102 F.3d 289, 293 (7th Cir. 1996) (both citing United States v. Silval, 71 F.3d 667, 670 (7th Cir. 1995)). Evidence is considered "material"

> if there is a reasonable probability that the disclosure of that evidence to the defense would have changed the result of the trial. There is a reasonable probability of a changed result where the government's suppression of evidence "undermines confidence in the outcome of the trial."

Payne, 102 F.3d at 293 (quoting Kyles v. Whitley, 115 S. Ct. 1555, 1556 (1995) and United States v. Bagley, 473 U.S. 667, 678 (1985)); see also United States. v. Hamilton, 107 F.3d 499, 509 (7th Cir.), cert. denied, 117 S. Ct. 2528 (1997); Gonzalez, 93 F.3d at 316; United States v. Maloney, 71 F.3d 645, 653 (7th Cir. 1995), cert. denied, 117 S. Ct. 295 (1996) (each reiterating that evidence is material if its suppression undermines confidence in the outcome of the trial).

The Government's Arguments Based on the Four-Part Test

Relying on cases decided under Rule 33, the government argues that defendants' motion fails each part of the four-part test required under that rule. As noted above, Brady, rather

than Rule 33, provides the requirements defendants must meet, and this makes a difference which is immediately apparent. The government initially argues that because the defendants knew prior to trial that their competitors had submitted stability data to the FDA, they fail the first part of the Rule 33 test. The government contends that it is not what the data shows, but rather that the data had been submitted to the FDA, which is important for Rule 33 purposes.

We would not be persuaded by this argument even if Rule 33 provided the governing test, because we think the relevant fact is not that the stability data had been submitted to the FDA, but that the data contained information indicating that Lactulose with a pH level as low as 2.5 was entirely stable and effective. But Brady, not Rule 33, applies to the situation, and the government's argument clearly does not fit a Brady analysis. As we shall see, the stability data in the possession of the government threw substantial doubt on its theory of the case and was therefore evidence favorable to the defense. The fact that the defendants knew stability data had been submitted to the government, without knowing what it showed -- and without any easy means of obtaining this proprietary information -- is irrelevant. There is no suggestion that the defendants knew or even had any reason to suspect prior to trial that the stability records contained information favorable to them.

Next, the government argues that the defendants failed to use due diligence to discover the stability information prior to trial. This second part of the Rule 33 test is not part of a Brady analysis, so it need not detain us long. The government sees no reason why the defendants did not seek the stability information from the competitors or from the FDA prior to trial, even though they had no way of knowing the effort would produce evidence favorable to them. It would not have

been a simple matter, nor can the court say at this time how it would have ruled had discovery motions been made. It is likely the competitors would have objected on the basis of the proprietary nature of the information, and the court probably would have applied a balancing test. This could have resulted in a finding that the probability of favorable evidence was too speculative to justify the intrusion. As far as the FDA itself is concerned, the government strenuously objected to the defendants' motion to produce the stability records even after the U.S.P. disclosure of what the records showed and the present motion had been filed by the defendants. The government argued that the work involved in locating and producing the records would be an enormous and unnecessary burden.

Even if the Rule 33 "due diligence" test applied, therefore, we believe it would not require the defendants to have undertaken pretrial discovery motions to obtain the competitors' stability data. It is by no means clear that, had they done so, they would have been successful.

In any event, the government cannot reasonably argue that defendants failed to do anything they needed to do in order to satisfy Brady. They moved repeatedly for production of Brady materials and both they and the court were assured by the government that all such materials would be produced, both those that were "exculpatory," and those which were "favorable" to the defense.[13] The defendants had a right to rely upon the government's obligation to produce favorable evidence even without such an assurance, but certainly with the assurance it was reasonable for the defendants to believe that no favorable evidence was being withheld.

---

[13] See p. [14a], supra.

The third part of the test under Rule 33 is that the newly discovered evidence must be "material and not merely impeaching or cumulative." The government has a variety of arguments as to why the stability data would have been irrelevant, confusing, and generally inadmissible. It contends, for one thing, that the evidence would have resulted in 'mini-trials' concerning the comparability of the various competitors' manufacturing processes and testing methods to those of ALRA to determine whether the competitors' results supporting the 2.5 pH level would be indicative of the safety of ALRA's Lactulose at the same level. In a curious begging of the question, the government argues that a major distinguishing feature of ALRA's Lactulose is that it had been injected with sodium hydroxide, as alleged in Counts 3, 4 and 6.

This kind of argument puts the burden in the wrong place. It could be that the competitors' stability data would ultimately prove unpersuasive to the jury, or even turn out to be inadmissible. But there is no reason at this point to think that either of these things would be true. The government's case was presented without any suggestion that the various standards to which it sought to hold the defendants were not supported by relatively uniform manufacturing processes and testing methods throughout the industry. For the government now to suggest that the pH range shown to be safe for the rest of the industry is inapplicable to ALRA is a new position for which it has no evidence. The stability data is apparently favorable and certainly bears on a material issue. It is not cumulative of any other evidence, but instead contradicts the evidence in the case concerning the low end of the safe pH range for Lactulose.

The fourth part of the Rule 33 test is that the newly discovered evidence would "probably lead to an acquittal in

the event of a new trial." How probable the acquittal must appear is not altogether clear under the cases, but that question need not be resolved because the test is different, or at least differently phrased, under Brady, and that is the test we will apply.

THE BRADY ANALYSIS

We now turn to the parties' arguments under Brady. The tests, it will be recalled, are that (1) the prosecution suppressed evidence; (2) the evidence was favorable to the defense; and (3) the evidence was material to an issue at trial.

Whether the Prosecution Suppressed Evidence

The government argues that it did not "suppress" favorable evidence because it did not know of the U.S.P. recommendation for a change in the pH range until after trial and, secondly, the defense could have obtained the stability data in the exercise of due diligence prior to trial.

There is some sleight of hand in the government's position. The primary favorable evidence is not the U.S.P. recommendation made in June of 1996, four months after the trial. The recommendation would probably be admissible at a new trial, and would undoubtedly be favorable to the defense. But the fact that the recommendation had not been made prior to the trial is irrelevant to the present motion. The favorable evidence that was suppressed is the stability data that was in the possession of the government for years prior to trial, which it does not deny it knew about and which it did not disclose to the defense. The failure to disclose this data satisfies the suppression requirement.

The second part of the government's argument concerning the suppression requirement switches to the stability data itself, rather than the U.S.P. recommendation or the competitors' application which prompted the recommendation, and suggests that the defendants could have obtained the data prior to trial. As we have already indicated in the discussion of Rule 33, it is not clear the court would have ordered pretrial production of the data. But we need not decide that question in order to do the analysis under Brady, which imposes an affirmative obligation on the government to produce favorable evidence. United States v. Gonzalez, 93 F.3d 311, 315 (7th Cir. 1996); United States v. Payne, 102 F.3d 289, 293 (7th Cir. 1996). The government expressly recognized its obligation to do just that and the defendants were justified in relying on that assurance.

The first requirement under Brady, that the prosecution suppressed evidence, has been satisfied.

The second and third Brady requirements are that the evidence was favorable to the defense and that it was material to an issue at trial. The last requirement comes down to whether the government's suppression of the evidence "undermines confidence in the outcome of the trial." Payne, 102 F.3d at 293.

In this case, the question of whether the stability data was favorable to the defense and the question of whether its suppression undermines confidence in the outcome of the trial are closely related and it will be convenient to discuss them together. The court answers both questions in the affirmative, for the following reasons.

There is no reason to doubt that the stability data showing the safety and therapeutic effectiveness of Lactulose at a pH

level as low as 2.5 would had been admissible at trial. The government offered evidence of the 3.0 - 7.0 range, and certainly any data from the same manufacturers tending to support a lower range was relevant. In fact, had the stability data been made available, it is likely the government's presentation on the "dangerousness" issue, if made at all, would have been quite different than it was.

The government argues that a 2.5 level would have had nothing to do with the evidence in the case because there was no contention that the Lactulose involved in Counts 3, 4, and 6 ever dipped to a pH level that low. The test records of ALRA showed that the Lactulose in question at the time sodium hydroxide was allegedly injected into the bottles was approximately 4.6.

However, it was the government's contention that at the time of the injections the Lactulose had degraded to a point where, had its true pH been tested and determined by the purchasers, they would have learned that the product had degraded so far that it was or would soon be unfit for use. This explained the defendants' need to distort the true pH by adding sodium hydroxide that would elevate the pH reading and mask the decomposition of the product. This was the prosecutors' theme from the beginning to the end of the trial: to avoid losing profits on these decomposed Lactulose lots, the defendants manipulated their pH levels in order to make them appear saleable.

The court does not recall that the government conceded in its argument to the jury that ALRA's records as to the actual pH of the product prior to the alleged injection were

accurate.[14] In fact, it was a major contention of the government throughout the trial that ALRA's records were, generally speaking, unreliable.[15] But more than that, the government repeatedly emphasized that the naturally occurring process of degradation was continuous, so that even if the actual pH level was at 4.6 when the injections occurred, the jury still could have concluded that the defendants recognized the need for a "booster" before distribution in order to avoid detection of a real problem that would appear shortly after distribution. Had the jury known that, according to stability data from the very manufacturers whose records had been used to support the recommended range of 3.0 to 7.0, the level of 2.5 was shown

> not to have any significant impact on the safety and quality of this product: it does not in any way affect the laxative properties of the

---

[14] Indeed, in one of its briefs filed in opposition to the present motion, on October 2, 1996, the government made this point:

> Second, based on the trial testimony of several witnesses, the laboratory testing conducted for and reported by the Defendants was not reliable.... Accordingly, the fact that ALRA's pH test results for lots 52-230-P and 52-231-P were recorded as being within its specification was neither surprising nor probative.

Government's Memorandum on the Question of Whether the Jury was Misled in Regard to the Matter of Lactulose Degradation, p. 24.

[15] If the court recalls correctly, Rule 404(b) "other acts" evidence was admitted, over defendants' objection, to support the government's contention that much of what the defendants did in the operation of their business could not be accepted at face value.

> product, and it does not affect the level of the related substances,[16]

the jury could well have reached a different conclusion as to whether the defendants had a motive to jiggle the pH of their product. The level of 4.6 is not in the danger zone, and according to the competitors' stability data, the level of 2.5 was not in the danger zone. It is this fact - that no problems of any kind had been reported at a 2.5 level - that would have cast serious doubt on the government's motive theory. And, if the defendants had no motive to order their employees to engage in the cumbersome process of injecting sodium hydroxide into the Lactulose bottles, it is difficult to understand why they would have done it. The government obviously recognized how essential it was to prove a motive for behavior which, absent a plausible motive, would be inexplicable.

In short, the lower the safe pH level, the less reason the defendants would have had to be nervous about a level of 4.6 or anything in that area, and the less motive they would have had to do what is charged in Counts 3, 4, and 6.

Moreover, the testimony of Dr. Senior concerning the dire consequences of ineffective Lactulose would have had no purpose if the government was not contending that the Lactulose in question was dangerous. Nor would the emphasis on that testimony in the prosecutor's opening statement and closing argument have made any sense if the government was not arguing that the Lactulose was in fact dangerous.

---

[16] U.S.P. bulletin of June 1996 quoted in full at p. [16a] supra.

The government attempts to avoid the consequence of its emphasis on the dangerousness of the Lactulose by pointing out that its argument to the jury was based in part on testimony that the injection of sodium hydroxide by itself rendered the product dangerous. This is another question-begging argument; it assumes the defendants did inject the Lactulose. We are concerned on this motion with the suppression of evidence that went to the question of whether they did so.

There is another respect in which the stability data is material, quite aside from the question of motive. The evidence at trial was that testing of the lots in question had shown the pH level of the Lactulose to have increased for no apparent reason after the date of the alleged injections. The goverrment's expert witness, Dr. Hicks, testified that the only explanation for this occurring in a closed container would be the addition of a base, such as sodium hydroxide. The defense expert, Dr. John Robyt, disagreed and said that the variations could be due to laboratory error. The government relied heavily on the testimony of Dr. Hicks in its final argument to the jury.

The competitors' stability data shows some variations in pH - going up, back down and then up again - that are arguably similar to those shown in the ALRA records for the lots in question. The government argues that the increases in pH shown in the competitors' stability data are significantly lesser increases than those shown in the ALRA test data. Whether this is true or not is a somewhat complicated factual question, and one properly for the jury.[17] But even if it were

---

[17] In its effort to distinguish the competitors' data, the government offers considerable factual information and analysis that is found neither in the data itself nor in the trial record.

true, it detracts little, if at all, from the materiality of the competitors' test data. Dr. Hicks testified that no increase could occur in a closed container without tampering. If the competitors' data show that any increases occurred in their laboratories, the data appears to contradict Dr. Hicks on this important question. Had the competitors' data been available to the jury, the defendants would have had support for their position that any unexplained variation in their own test results could have been due to laboratory error. There may be other or better arguments the defendants could have made.

The government argues that the evidence of the defendants guilt on Counts 3, 4 and 6 was so overwhelming that the competitors' stability data would have made no difference to the jury. This is not how the court remembers it. The description of the injection process given by the various employees who allegedly did it seemed unlikely in the extreme, unless there was some compelling motive for the defendants to have required them to engage in such a procedure. Not all of the employees who would have known about the incident agreed that it had occurred. Both of the Bhutanis denied that it had occurred. It seemed to the court at the time that the verdict could have gone either way, and, of course, there is no way of knowing how close the jury thought the question was. One thing that can be said for certain is that if the jury had entertained a reasonable doubt as to whether the defendants had a plausible motive for engaging in what otherwise would have been bizarre behavior, it could not have found the defendants guilty on Counts 3, 4 and 6.

The government's suppression of the evidence concerning the competitors' stability data seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4 and 6. The court concludes that the defendants have satisfied the

requirements of Brady v. Maryland and are entitled to a new trial on these counts.

The Spillover Question

The question remains whether the suppression of evidence specifically relating to Counts 3, 4 and 6 undermines confidence in jury's verdict on the other counts of conviction. The defendants argue that it does, inasmuch as the jury must have been affected in their consideration of the other counts by their finding that the defendants, motivated by a desire for profit, sold defective Lactulose that would be used by unsuspecting patients for whom it would pose a risk of serious injury or death. The remaining counts of the indictment all charged the same kind of shoddy, unscrupulous behavior, motivated by desire for profit and indifference to public health. The government's description of these counts, and its explanation of why there was no prejudice that could have spilled over on to them, is wholly unpersuasive. Indeed, merely quoting the government's argument exposes the close connection among all the counts on which defendants were convicted and the consequent likelihood of a spillover effect:

> Moreover, the absence of competitors' stability data could have had no 'spill-over' effect on the other counts of conviction unrelated to Lactulose stability (i.e. counts relating to the leaking Lactulose Drums, the K+10 contaminated with a metal pipe, and the HITS training program, and the conspiracy which includes various recordkeeping deficiencies), as the jury found ample evidence on those counts.

> Finally, contrary to Defendants' claim, the jury's verdict was in no way tainted by the Government's theme (articulated in its opening statement and closing argument) that ALRA's modus operandi was to sacrifice the public health to make a profit. This theme was clearly borne out by the evidence relevant to the counts of conviction: selling Lactulose adulterated with sodium hydroxide injections (i.e., Count Three, Four, and Six); selling Lactulose from leaking drums (i.e., Counts Seven and Eight); selling K+10 with fragments of metal pipes ground up in it (i.e., Count Ten); and failing to employ trained technicians in manufacturing human pharmaceuticals (i.e., Count Fifteen).[18]

The court agrees with the defendants. All counts of conviction were entwined with the government's profit motive theory and its contention that the defendants would cut any corners they had to regardless of the consequences to public health. A finding that the defendants were so motivated could well have provided the basis for the jury's verdict on the other charges, each of which was vigorously contested. It is true that the defendants were found not guilty on some counts and that the jury failed to reach a verdict on others. Any effort to reconcile the different results would be entirely speculative, and it is impossible to conclude from those results that the Brady violation had nothing to do with the jury's conclusion on any count where guilt was found. The court has the same

---

[18] Government's Opposition to Defendants' Post-Trial Motion for a New Trial Based on Newly Discovered Lactulose Stability Evidence, filed June 16, 1997, pp. 39-40.

lack of confidence in the verdict on those counts as it does on Counts 3, 4 and 6.

CONCLUSION

Because of the government's violation of Brady v. Maryland, each of the defendants is granted a new trial on each count of conviction.

DATED: December 1, 1997

ENTER:

_____

John F. Grady, United States District Judge

APPENDIX C

United States Court of Appeals
For the Seventh Circuit
Chicago, Illinois 60604

UNPUBLISHED

October 4, 1999

Before

Hon. WILLIAM J. BAUER, Circuit Judge

Hon. KENNETH F. RIPPLE, Circuit Judge

Hon. TERENCE T. EVANS, Circuit Judge

UNITED STATES OF AMERICA, *Plaintiff-Appellant,*	)	Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.
No. 98-1154	)	No. 98 CR 585
BALDEV RAJ BHUTANI, NEELAM BHUTANI, and ALRA LABORATORIES, INC., *Defendants-Appellees.*	)	Judge F. Grady, *Judge*

Defendants-appellees filed a petition for rehearing and petition for rehearing en banc. No judge in regular active service has requested a vote on the petition for rehearing en banc, and all of the judges on the panel have voted to deny rehearing. The petition for rehearing is therefore DENIED.